

5741-01-EJF  
Application No. 09/284,858

### REMARKS

#### I. Status of the Application

This paper responds to a Non-Final Office Action, which was mailed on March 15, 2004. The original application was filed with claims 1-7. In response to an Office Action mailed April 17, 2000, which rejected all of the claims, Applicant amended claims 1 and 3 and added claims 8-20. A subsequent Final Office Action, which was mailed on February 9, 2001, maintained the rejection of claims 1-7, rejected newly added claims 8-10, and withdrew from consideration claims 11-20 as being drawn to a non-elected invention. Following the February 9, 2001 Final Office Action, Applicant filed an After Final Amendment, which was not entered. On May 7, 2001, Applicant filed a Continued Prosecution Application, together with a Preliminary Amendment that amended claim 1 and canceled claims 8 and 9. An Office Action mailed on August 15, 2001, again rejected claims 1-7 and 10. Applicant filed a response on December 17, 2001, presenting arguments regarding patentability. A Final Office Action was mailed on April 16, 2002, which maintained the rejection of claims 1-7 and 10. In response, Applicant submitted an After Final Amendment on June 13, 2002, which was refused entry in a subsequent Advisory Action. Applicant filed a Request for Continued Examination (RCE) on July 16, 2002. As part of the RCE, Applicant submitted an After Final Amendment, which amended claim 1. On December 11, 2002, Applicant responded to a Species Election Requirement that was mailed on November 12, 2002. On July 16, 2003, Applicant filed an amendment in response to an Office Action mailed on March 17, 2003, which rejected claims 1-5 and 10, and withdrew claims 6 and 7 from consideration. A Final Office Action was mailed on October 22, 2003. Applicant submitted an After Final Amendment on January 22, 2004, which canceled claims 3, 4, 6, 7, and 11-20 and added new claims 21-23.

The present amendment amends claims 1, 2, 5, 22, and 23 and adds claims 24-27. Accordingly, claims 1, 2, 5, 10, and 21-27 are currently under consideration. Applicant respectfully requests reconsideration of the pending claims in view of the above

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amendment and the following remarks. By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

## II Two-Month Extension of Time

Applicant hereby petitions for a two-month extension of time to reply and has enclosed the requisite fee. The present Office Action, which was mailed on March 15, 2004, set a shortened statutory period for reply of three months, making any response due on June 15, 2004. Applicant is filing this response on August 3, 2004, which is within the second month following the expiration of the shortened statutory period for reply.

## III. Amendment of Claims 1, 2, 5, and 21-23

Claim 1 has been amended to clarify that the solid pharmaceutical dosage form is "an orally deliverable form." Additionally, claim 1 and claim 21 have been amended so that they no longer use the term "suitable." Claims 2, 5, 22, and 23 have been amended to correct claim informalities. Applicant submits that none of the amendments introduces new matter.

## IV. New Claims 24-27

New claims 24-27 depend on claim 1 and recite ranges for the amount of active agent in the solid particulate dispersion. These claims are fully supported in the application as filed. See, for example, the application at page 2, lines 19-27.

## V. Rejection of Claims 1 and 5 Under 35 U.S.C. § 102(b)

The Office Action rejected claims 1 and 5 under 35 U.S.C. § 102(b) as allegedly being anticipated by Japan Patent Document 58-079915 ('915). Applicant respectfully traverses the rejection.

Applicant submits that the '915 reference neither anticipates nor renders obvious the claimed invention because it does not teach or suggest every limitation in claim 1. As

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noted above, Applicant has amended claim 1 to clarify that the solid pharmaceutical dosage form is an "orally deliverable form." The '915 reference does not disclose orally deliverable dosage forms, but instead describes "elongated chemical agents" for "local treatment," i.e., non-systemic treatment. See '915 reference (English translation) at pages 1-2, first paragraph under "Detailed Description of the Invention." Moreover, the described elongated chemical agents have "narrow diameter," are "needle-shaped," and are therefore inappropriate for use as oral dosage forms. See '915 reference at page 2, first full paragraph. Since the '915 reference does not describe oral dosage forms, it cannot anticipate or render obvious claim 1.

Furthermore, Applicant submits that there is no motivation or suggestion to modify the '915 reference to arrive at the present invention because to do so would render the reference unsatisfactory for its intended purpose. If a proposed modification would render the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordan*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984), cited in *Manual of Patent Examining Procedure* § 2143.01 (8th Ed. 2001). As noted above, the express purpose of the '915 reference is to provide elongated chemical agents for local or non-systemic treatment. Such agents are needle-like and therefore inappropriate for use as oral dosage forms. If, however, the chemical agents had an "orally deliverable form" that was not needle-like, they would be unsatisfactory for local or non-systemic treatment. Applicant therefore submits that claim 1, and all claims that depend on claim 1, are patentable over the '915 reference.

VI. Rejection of Claims 1, 2, 5, 10, and 21-23 Under 35 U.S.C. § 112

The Office Action rejected claims 1, 2, 5, 10, and 21-13 under 35 U.S.C. § 112 as allegedly being indefinite for using the word "suitable." Although Applicant disagrees with the rejection, Applicant has removed the word "suitable" from claims 1 and 21, thereby obviating this rejection.

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VII. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that all fees required to file the present amendment have been identified in a fee transmittal that accompanies this response. If, however, any other fees are required to file this paper, and such fees have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

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